

Remarks

The Official Action dated January 12, 2005 has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set in the Official Action. Therefore, the initial due date for response is April 12, 2005.

At page 2 of the Official Action, the Examiner has withdrawn the finality of the previous Official Action and has objected to the specification for alleged improper incorporation of subject matter. The Examiner requires that Applicants amend the specification and claims to include the hybridization conditions described by Amasino et al. These amendments have been made thereby rendering the foregoing objection moot. Inasmuch as Amasino et al. was properly cited in the application as filed, it is submitted that the amendment to the specification does not constitute new matter.

Claims 29-35, 37, 48, 64-70 and 72-74 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the invention at the time the application was filed.

The Examiner has also rejected claims 29-35, 37, 48, 64-70 and 72-74 asserting that the specification fails to adequately enable the claimed subject matter.

Applicants submit that the claims as presently amended are in condition for allowance. Each of the above-noted rejections is traversed for the reasons set forth below.

**THE SUBJECT MATTER OF CLAIMS 29-35, 37, 48, 64-70, 72-74 AS  
AMENDED AND NEW CLAIM 75 IS FULLY ENABLED AND DESCRIBED IN THE  
SPECIFICATION AS FILED**

The Examiner has rejected claims 29-35, 37, 48, 64-70 and 72-74 under 35 U.S.C. §112, first paragraph asserting that the specification does not provide an adequate written description of the subject matter encompassed by these claims. Specifically, the Examiner objects to the inclusion of sequences encoding an enzymatically active fragment of SEQ ID NO: 2 in claim 29. It is the Examiner's position that Applicants have not described nucleic acid sequences having this characteristic. Applicants disagree.

The claims require that the recited sequences encode a protein which is SEQ ID NO: 2, an enzymatically active fragment of SEQ ID NO: 2 or a sequence which hybridizes to the nucleic acid encoding SEQ ID NO: 2 under stringent conditions which also possesses RdRP activity. Such a sequence is fully described in the specification. Applicants have provided the full length sequence of SEQ ID NO: 1 which encodes the RdRP of SEQ ID NO: 2 of the invention. Applicants have also set forth stringent hybridization conditions for identifying polynucleotides which hybridize to the nucleic acid of SEQ ID NO: 1. Inasmuch as the full sequence encoding RdRP is provided in the application, it cannot be reasonably be maintained that fragments of this sequence which possess RdRP activity do not have an adequate written description. Clearly, it is well within the purview of the skilled person to truncate SEQ ID NO: 2 in a stepwise fashion to identify those fragments which are enzymatically active. Likewise, once a RdRP encoding sequence is identified using the hybridization conditions described in the specification and encompassed by the claims, it would be routine to truncate such a sequence to identify enzymatically active fragments thereof. Assays for assessing RdRP activity of such fragments are provided in the

specification at pages 31-32. As noted in the MPEP at § 2163, To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Clearly the skilled person would appreciate that the present inventors were in possession of the RdRP molecules encompassed by the claims. Moreover, the instant application is a continuation application of application 08/811,583 now US Patent 6,218,142. Notably, the language that the Examiner is presently objecting to was found to be enabled and fully described in the parent application from which the present application claims priority. See claim 1 of the '142 patent which was found to satisfy the relevant sections of 35 U.S.C. §112, first paragraph. Applicants are frankly confounded by the conflicting positions taken by the USPTO in this family of patent applications. Inasmuch as the language in the claims directed to RdRP sequences is essentially identical, it is respectfully submitted that the rejection of claims 29-35, 37, 48, 64-70 and 72-74 for inadequate written description is improper and should be withdrawn.

Claims 29-35, 37, 48, 64-70 and 72-74 are also rejected under 35 U.S.C. §112, first paragraph. It is the Examiner's position that the specification does not provide enablement for the sequences encompassed by the claims.

A rejection under 35 U.S.C. §112, first paragraph, based on inadequate enablement is proper only when the rejected claim(s) is (are) of such breadth as to read on subject matter to which the specification is not enabling. In re Borkowski, 164 U.S.P.Q. 642 (CCPA 1970). Moreover, it is settled law that whenever the adequacy of enablement provided by an applicant's specification is challenged, the PTO has the initial burden of giving reasons, supported by the record as a

whole, why the specification is not enabling. In re Armbruster, 185 U.S.P.Q. 152 (CCPA 1975). Indeed, a properly supported showing that the disclosure entails undue experimentation is part of the PTO's initial burden under §112, first paragraph. In re Angstadt, 190 U.S.P.Q. 214 (CCPA 1976).

Applicants respectfully submit that the skill in the art of molecular biology and the creation of transgenic plants is quite high. The skilled artisan in this field could readily generate sequences of SEQ ID NO: 2, or identify sequences which hybridize to SEQ ID NO: 1 under stringent conditions and test them for RdRP activity based on the disclosure provided in the specification without undue experimentation. Furthermore, truncating sequences so identified followed by testing them in an RdRP assay is routine in the art and while a certain amount of experimentation is necessary, it would not be considered undue by the skilled person. Again, a review of the prosecution history of this family of cases indicates that the subject matter of the present claims as it relates to nucleic acid molecules has previously been found to be enabled by the specification and in conformance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, Applicants submit that the present rejection is inconsistent with the position taken during the prosecution of the parent application and request that the rejection of the claims under 35 U.S.C. §112, first paragraph be withdrawn.

#### CONCLUSION

The present communication is completely responsive to the issues raised in the Official Action of January 12, 2005. Applicants believe that the claims as they stand are in condition for ready allowance. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a

telephone interview, the Examiner is requested to telephone  
the undersigned attorney at the phone number given below.

Respectfully submitted,  
DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By   
Kathleen D. Rigaut, Ph.D., J.D.  
Registration No. 43,047

Telephone: (215) 563-4100  
Enclosure: Amasino et al.